MAY 1 6 2002

# 510(k) SUMMARY, K020512

## Medical Technology & Innovations, Inc.

## MTI ST#1 Silicone Pessary

## March 14, 2002

**Submitter Information:**


Submitter's Name: Larry W. James, P.A.
Senior VV – Research & Development
Medical Technology & Innovations, Inc.
1072 N.W. High Point Drive
Lee's Summit, MO 64081

Phone: (816) 525-6677
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**Device Name:**

Proprietary name: MTI ST#1 Silicone Pessary

Common Name: Vaginal pessary

Classification Name: Vaginal pessary

**Predicate Device Equivalence:**

Substantial equivalence is claimed to the DesChutes Medical Products, Inc. Pelvx Incontinence Ring, cleared for commercial distribution per K974116, and to the Milex Silicone Gehrung with Knob Pessary, 510(k) number unknown.

**Device Description:**

The MTI ST#1 Silicone Pessary is geometrically shaped such that when inserted in the patient's vagina, the urethra is aligned between the legs of the device and the bladder is fully supported, thus allowing the bladder to function normally.

**Intended Use:**

The MTI ST#1 Silicone Pessary is intended for prescription use to be used in the treatment of genuine stress urinary incontinence. It is not intended to be used while sleeping and thus must be removed on a daily basis before going to bed.

**Device Classification:**

Class II, 21 CFR 884.3575, Product Code HHW

**Predicate Devices:**

DesChutes Medical Products, Inc. PelvX Incontinence Ring, K974116

Milex Silicone Gehrung Folding Pessary, 510(k) number unknown

**Comparison of Technological Characteristics:**

The MTI ST#1 Silicone Pessary has the same technological characteristics as the predicate devices.

**Summary of Device Evaluation:**

Information on this and similar devices demonstrates that the MTI ST#1 Silicone Pessary performs as intended. Biocompatibility data demonstrates that the device is nonirritating and nontoxic.

**Conclusions:**

Based on the above, we concluded that the MTI ST#1 Silicone Pessary is substantially equivalent to a legally marketed predicate device and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2002

Larry W. James, P.A.
Senior Vice President
Research and Development
Medical Technology
& Innovations, Inc.
3725 Investment
RIVIERA BEACH FL 33404

Re: K020512
Trade/Device Name: MTI ST#1 Silicone Pessary
Regulation Number: 21 CFR 884.3575
Regulation Name: Vaginal pessary
Regulatory Class: II
Product Code: 85 HHW
Dated: February 14, 2002
Received: February 15, 2002

Dear Mr. James:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K020512

**Device Name:**

MTI ST#1 Silicone Pessary

**Indications for Use:**

The MTI ST#1 Silicone Pessary is intended for prescription use to be used in the treatment of genuine stress urinary incontinence. It is not intended to be used while sleeping and thus must be removed on a daily basis before going to bed.

*Prescription Use* ✓

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020512